

1 We claim:

2 1. A transcutaneous device dressing for use with a transcutaneous medical device which
3 has punctured the skin of a patient and which has a portion of the medical device protruding
4 from the skin, comprising:

5 a top and a bottom dressing, both being formed from a flexible material and having
6 upper and lower surfaces, the lower surfaces being skin facing when the dressing is in use;
7 the bottom dressing having a slit formed therein extending from one edge inwardly to
8 a termination point within the confines of the bottom dressing;

9 an anti-microbial material provided without the use of adhesives at the upper and
10 lower surfaces of the bottom dressing, and at least at the lower surface of the top dressing;

11 whereby, in use, the bottom dressing is placed next to the skin, the slit allowing the
12 bottom dressing to surround the puncture site such that the lower surface of the bottom
13 dressing is in contact with the skin and the upper surface of the bottom dressing is in contact
14 with a portion of the medical device protruding from the skin, and the top dressing is placed
15 above the puncture site such that its lower surface is in contact with a portion of the medical
16 device protruding from the skin, thereby exposing a portion of the medical device protruding
17 from the skin from above and below to the anti-microbial activity of the anti-microbial
18 material.

19 2. A method of dressing the puncture site of a transcutaneous medical device to limit
20 infection by microorganisms from the surrounding skin and a portion of the medical device
21 that protrudes from the skin of a patient, comprising:

22 providing a transcutaneous device dressing, comprising:

23 a top and a bottom dressing, both being formed from a flexible material and having
24 upper and lower surfaces, the lower surfaces being skin facing when the dressing is in use;
25 the bottom dressing having a slit formed therein extending from one edge inwardly to
26 a termination point within the confines of the bottom dressing; and

27 an anti-microbial material provided without the use of adhesives at the upper and
28 lower surfaces of the bottom dressing, and at least at the lower surface of the top dressing;

29 sliding the bottom dressing in place next to the skin using the slit to allow the bottom
30 dressing to surround the puncture site at the termination point such that the lower surface of
31 the bottom dressing is in contact with the skin surrounding the puncture site and the upper
32 surface of the bottom dressing is in contact with a portion of the medical device protruding

1 from the skin;

2 applying the top dressing above bottom dressing such that the lower surface of the top
3 dressing is in contact with a portion of the medical device protruding from the skin;

4 depending on the anti-microbial material, applying a water or alcohol based
5 electrolyte to the dressing to release the anti-microbial material; and

6 fixing the top and bottom dressings to the skin.

7 *Sub 7A* 3. The dressing or method as set forth in claim 1 or 2, wherein:

8 the top and bottom dressings are formed from a unitary dressing and are joined
9 together and divided by a fold line.

10 4. The dressing or method as set forth in claim 3, wherein:

11 the anti-microbial material is a coating of an anti-microbial metal applied to the upper
12 and lower surfaces of the bottom dressing, and at least to the lower surface of the top
13 dressing.

14 5. The dressing or method as set forth in claim 4, wherein the slit is formed from the
15 edge of the bottom dressing which is parallel to the fold line.

16 6. The dressing or method as set forth in claim 5, wherein the top and bottom dressings
17 are formed from multilayered, laminated dressing materials.

18 7. The dressing or method as set forth in claim 6, wherein the top and bottom dressings
19 are formed from:

20 a first, skin facing layer formed of a perforated, non-adherent material;

21 a second layer laminated to the first layer, and being formed of an absorbent material;

22 and

23 a third layer laminated to one or both of the first and second layers.

24 8. The dressing or method as set forth in claim 7, wherein the anti-microbial metal
25 coating is formed on the first and the third layers.

26 9. The dressing or method as set forth in claim 8, wherein the top and bottom dressings
27 are sized so as to provide coverage of the portion of the medical device protruding from the
28 skin of at least about 5 mm.

29 10. The dressing or method as set forth in claim 9, wherein the anti-microbial metal
30 coating is a thin film containing at least one anti-microbial metal, said anti-microbial metal
31 being formed with sufficient atomic disorder such that the thin film, in contact with an
32 alcohol or water based electrolyte, releases ions, atoms, molecules or clusters of the anti-

1 microbial metal into the alcohol or water based electrolyte at a concentration sufficient to
2 provide a localized anti-microbial effect on a sustainable basis.

3 11. The dressing or method as set forth in claim 10, wherein the anti-microbial metal
4 coating comprises:

5 a base layer of a partly reflective material capable of generating an interference colour
6 when covered with a partly reflective, partly light transmissive top layer:

7 a top layer formed over said base layer, said top layer being a partly reflective, partly
8 light transmissive thin film containing at least one anti-microbial metal and having a
9 thickness such that a first or second order interference colour is produced, said top layer
10 having a refractive index different from that of the base layer, and anti-microbial metal being
11 formed with sufficient atomic disorder such that the top layer, in contact with an alcohol or
12 water based electrolyte, releases ions, atoms, molecules or clusters of the anti-microbial metal
13 into the alcohol or water based electrolyte at a concentration sufficient to provide a localized
14 anti-microbial effect on a sustainable basis.

15 12. The dressing or method as set forth in claim 11, wherein the material in the base layer
16 is a metal selected from the group consisting of Ag, Au, Pt, Pd, Cu, Ta, Al and alloys or
17 compounds of one or more of these metals, in a partly reflective form, and wherein the anti-
18 microbial metal in the top layer is selected from the group consisting of Ag, Au, Pt, Pd, Ir,
19 Sn, Cu, Sb, Bi, Zn, and alloys or compounds of one or more of these metals.

20 13. The dressing or method as set forth in claim 12, wherein the material in the base layer
21 and the anti-microbial metal in the top layer is a metal selected from the group consisting of
22 Au, Ag, Pt, Pd, and Cu in a partly reflective form, and is formed by vapour deposition with
23 sufficient atomic disorder such that the top layer, in contact with an alcohol or water based
24 electrolyte, releases ions, atoms, molecules or clusters of the anti-microbial metal into the
25 alcohol or water based electrolyte at a concentration sufficient to provide a localized anti-
26 microbial effect on a sustainable basis.

27 14. The dressing or method of claim 13, wherein the metal in the base and top layer is Ag,
28 Pt or Au.

29 15. The dressing or method as set forth in claim 14, wherein the top layer is a thin film of
30 a composite material formed by co-, sequentially or reactively depositing the anti-microbial
31 metal by vapour deposition in a matrix with atoms or molecules of a different material to
32 create atomic disorder in the matrix, said different material being selected from the group

consisting of biocompatible metals, oxygen, nitrogen, hydrogen, boron, sulphur or halogens, or an oxide, nitride, carbide, boride, halide, sulphide or hydride of either or both of an anti-microbial metal or a biocompatible metal.

16. The dressing or method as set forth in claim 15, wherein the biocompatible metal is selected from the group consisting of Ta, Ti, Nb, V, Hf, Zn, Mo, Si and Al.

17. The dressing or method as set forth in claim 15, wherein the anti-microbial metal is silver and said different material is one or both of silver oxide and atoms or molecules containing oxygen trapped or absorbed in the matrix.

18. The dressing or method as set forth in claim 17, wherein the top layer is less than 400 nm thick, and the base layer is at least 25 nm thick.

19. The dressing or method as set forth in claim 18, wherein the top layer is between 5 and 210 nm thick, and the base layer is at least 60 nm thick.

20. The dressing or method as set forth in claim 19, wherein the top layer is about 40 - 160 nm thick and the base layer is at least about 300 nm thick.

21. The dressing or method as set forth in claim 10 or 20, wherein the first and optional third layers are formed from a non-woven, perforated, non-adherent high density polyethylene material.

22. The dressing or method as set forth in claim 21, wherein the second layer is formed from a non-woven, absorbent rayon/polyester material.

23. The method as set forth in claim 2, wherein the dressing is fixed in place with an occlusive or semi-occlusive layer which maintains the dressing in a moist condition.

24. The method as set forth in claim 23, wherein the occlusive or semi-occlusive layer is an adhesive film.

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